Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2007 has been entered.

Response to Amendment

Applicant's response of 30 October 2007 has been received and entered. Claims 1-58 have been canceled and claims 59-61 have been added. Claims 59-61 are currently pending and under examination in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 30 October 2007 have been fully considered, but are not persuasive.

Terminal Disclaimer

The terminal disclaimer filed on 30 October 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,288,301 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 59 recites that the gastrin/CCK receptor ligand or EGF receptor ligand is “is about 1.4 to about 35 mg”. However, there is no basis for this limitation in the instant specification as filed.

Applicant points to basis for this limitation at page 12 of the specification (lines 29-32). However, this portion of the specification refers to dosages and does not relate to the amounts listed in the claims. Applicant argues at page 3 of the response that "unit dosages are routinely calculated based on an about 70 kg human subject". However, this still does not lend support for what is specifically claimed because the

specification did not contemplate this based on the disclosure which fails to suggest this claim limitation. Therefore, this constitutes new matter.

Claim Rejections - 35 USC §§ 102 and/or 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 59-61are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Conteas et al. (Proc. Soc. Exp. Biol. Med. 184(3): 307-311, 1987) for the reasons of record as applied to claims 44-56 in the previous Office action(s).

As stated previously, Conteas et al. teach the administration of gastrin and EGF, either alone or in combination (see page 308, column 1, lines 12-16). The gastrin and EGF were procured from Peninsula Laboratory and Collaborative Research, respectively. Therefore, it would be fair to conclude that the gastrin and EGF were in

vials for shipment and were in close proximity to one another at some point in time (i.e. in the refrigerator or in a cabinet – together in a refrigerator or a cabinet could be considered a "container"). This would consititute a "kit" because the two components were together for use alone or in combination.

Conteas teach the use of gastrin and EGF in combination, therefore, placing the two components together in a "kit" is either anticipated by Conteas (as explained above) or is clearly obvious based on the fact that Conteas teach use of the two components together for a given purpose absent evidence to the contrary. Applicant asserts that Conteas only discusses use of gastrin and EGF in vitro, and therefore, Conteas do not teach the administration of gastrin and EGF for therapeutic applications, and a kit for therapeutic applications would not reasonably flow from the teachings of the publication. Applicant's argument has been fully considered, but is not persuasive. However, intended use is not a limitation that needs to be met by the prior art – if the composition is in the prior art, then it meets the limitations of the claims. Furthermore, because Conteas teach the coadministration of the two components of the kit, Conteas clearly teach motivation for putting the two components together if not already anticipating the combination. With regard to therapeutic applications, Conteas teach that the coadministration of gastrin and EGF stimulate the proliferation of small intestine crypt cells, which has direct application to treatment of a number of conditions in mammals requiring proliferation of cells of the intestine. Therefore, Conteas et al. clearly teach the motivation to use sterile, pharmaceutically acceptable forms of gastrin and EGF

together and because one would want to stimulate crypt cells in a person, therapeutics for human use would also be *prima facie* obvious, absent evidence to the contrary.

The claims include the limitation of an amount of either gastrin/CCK receptor ligand or EGF receptor ligand at about 1.4 to about 35 mg. The Conteas reference does not state what amount of ligand was present in the containers prior to removal of the ligand for dilution and administration. Therefore, Conteas might anticipate the claims. However, in the event that Conteas did not have a container of gastrin/CCK receptor ligand or EGF receptor ligand with about 1.4 to about 35 mg present, it would have been obvious at the time of the instant invention to have any amount of ligand present in the container. This is because the "therapeutically effective" amount of ligand depends on the use of the ligand (i.e. for what condition the ligand is to be therapeutically effective for) as well as the purpose for which one is administering the ligand (i.e. for administration to a person or possible for cell culture use). Therefore, it would be obvious to have larger amounts in a container, and mg amounts are common amounts which are usually found in containers. Therefore, the claims are either anticipated or obvious over Conteas, absent evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/

Primary Examiner, Art Unit 1647